

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of the effect of cervical proprioceptive exercises in addition to conventional physiotherapy with isolated conventional physiotherapy on relative proprioceptive weighting of the cervical spine and postural control in chronic non-specific neck pain individuals.

Protocol summary

Study aim

Investigating of the effect of Adding Exercises focused on neck proprioception to conventional physical therapy on relative proprioceptive weighting of the cervical spine and postural control in Patients with non-specific chronic neck pain.

Design

A randomized clinical trial, consisting of two parallel, double-blind, groups. Sample size will be calculated using G * power software based on mean difference and standard deviation of the main study variables to be obtained in the pilot study (n = 5).

Settings and conduct

Accessible population is adult men and women with non-specific chronic neck pain will refer to USWR outpatient clinics. Patients should not contact with each other. The assessor will not be aware of the grouping and treatment plan of the subjects. Both groups will be treated by experienced physiotherapist. Subjects will practice twice daily for 5 weeks.

Participants/Inclusion and exclusion criteria

Individuals with nonspecific chronic neck pain with a duration of at least 3 months (either permanent or episodic). The pain should be experienced in the sub-occipital (to T1) and/or the upper trapezius muscle. They should not have received physiotherapy in the past 6 months to treat neck pain. They should stand upright and their neck range of motion should not limited.

Intervention groups

We should have two treatment groups. One group will receive conventional physical therapy and the other group will receive cervical proprioceptive exercises in addition to the conventional treatment. In both groups, participants will receive PT treatment 3 sessions/week for a duration of 5 weeks. They'll all be asked to do their home exercise twice a day and record exercises

performance in their schedule sheet.

Main outcome variables

Sway Velocity, Sway Range, Relative Proprioceptive Weighting

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191130045552N1**

Registration date: **2020-01-12, 1398/10/22**

Registration timing: **prospective**

Last update: **2020-01-12, 1398/10/22**

Update count: **0**

Registration date

2020-01-12, 1398/10/22

Registrant information

Name

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-01-21, 1398/11/01

Expected recruitment end date

2020-09-22, 1399/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of cervical proprioceptive exercises in addition to conventional physiotherapy with isolated conventional physiotherapy on relative proprioceptive weighting of the cervical spine and postural control in chronic non-specific neck pain individuals.

Public title

Comparison of the effect of cervical proprioceptive exercises in addition to conventional physiotherapy with isolated conventional physiotherapy on relative proprioceptive weighting of the cervical spine and postural control in chronic non-specific neck pain individuals.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Individuals with nonspecific chronic neck pain with a duration of at least 3 months (either permanent or episodic).The pain should be experienced in the sub-occipital area and/or the upper trapezius muscle. The average pain intensity during 3 weeks prior to testing session should be between 3.5 and 6.5 and pain intensity in the testing day should be less than 6.5. based on the patient's physician's diagnosis, the neck pain should not be associated with any specific lesion or injury, with no symptoms of radicular pain and upper limbs and no pathoanatomic diagnosis. By asking the patient, we make sure that patients do not receive any physical therapy or exercise therapy for the neck during the study. The patient should have passed at least primary school level of education. Included patients should have at least 60 degrees of neck extension without sever symptom exacerbation. In the past 6 months, they have not received physiotherapy for neck pain. Ability to stand upright. The patients know Persian language. The patients did not perform Jaw-Temporal surgery. The patients should not have Severe mental illnesses requiring medication. Not participating regular exercising.

Exclusion criteria:

Positive Dix Hallpike test that indicates vestibular system dysfunction. Dissatisfaction with continuing tests. Inability to perform or complete study tests due to exacerbation of symptoms.

Age

From **18 years** old to **55 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients are allocated into two groups of proprioceptive (PT) and conventional physiotherapy treatment with Randomization.com software through Random Permutations. This method provides the researcher with a predetermined random order by the software, thus prior to recruitment, the allocation of every participant is determined. Each subject will enter the study based on the order of their entry (number 1, subject 2 and ...). Randomization will be done on subjects who are all patients with neck pain and are not different in all group characteristics and independent variables, so none of our independent variables play a role in randomization.

Blinding (investigator's opinion)

Double blinded

Blinding description

Grouping is associated with the patient kept unaware of being in the case or control group and the treatment regimen of the other group. The assessor will not be aware of the grouping and treatment plan of the subjects.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of University of Social Welfare and Rehabilitation Sciences

Street address

University of Social Welfare and Rehabilitation Sciences, Koodakyar Ave, Daneshjoo Blve, Evin

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Tehran

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Postal code

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Approval date

2019-10-21, 1398/07/29

Ethics committee reference number

IR.USWR.REC.1398.095

Health conditions studied

1

Description of health condition studied

Non-specific chronic neck pain

ICD-10 code

M54. 2

ICD-10 code description

Pain, cervical (neck), chronic, more than 3 months. Discomfort or more intense forms of pain that are localized to the cervical region. This term generally refers to pain in the posterior or lateral regions of the neck.

Primary outcomes

1

Description

Sway Velocity

Timepoint

Up to one week before and after the intervention

Method of measurement

Force Plate

2

Description

Sway Range

Timepoint

Up to one week before and after the intervention

Method of measurement

Force Plate

3

Description

Relative Proprioceptive Weighting

Timepoint

Up to one week before and after the intervention

Method of measurement

Force Plate

Secondary outcomes

1

Description

Pain Intensity

Timepoint

Up to one week before and after the intervention

Method of measurement

Visual Analog Scale

2

Description

Disability

Timepoint

Up to one week before and after the intervention

Method of measurement

Neck Disability Index

3

Description

Fear Avoidance

Timepoint

Up to one week before and after the intervention

Method of measurement

Tampa Scale for Kinesiophobia

4

Description

Sway Area

Timepoint

Up to one week before and after the intervention

Method of measurement

Force Plate

5

Description

Sway Path Length

Timepoint

Up to one week before and after the intervention

Method of measurement

Force Plate

6

Description

Maximum Lyapunov Exponent

Timepoint

Up to one week before and after the intervention

Method of measurement

Force Plate

Intervention groups

1

Description

Control group: The control group will receive conventional physical therapy program (CPT). Each treatment session takes 60 minutes. Patients are asked to perform conventional physiotherapy exercises at home, twice a day for 5 weeks, and record their exercises in a structural scheduled. They will receive electrotherapy intervention at clinic sessions.

Category

Rehabilitation

2

Description

Intervention group: The intervention group will be received proprioceptive training (PT) in addition to the conventional program. Each treatment session takes 120 minutes. Patients are asked to perform conventional physiotherapy exercises at home, twice a day for 5 weeks, and record their exercises in a structural scheduled. They will receive electrotherapy intervention

at clinic sessions. The PT group will be additionally trained by proprioceptive exercises at clinic sessions. The patients in this group will practice head relocating exercise under supervision of a trained physical therapist.

Category

Rehabilitation

Recruitment centers**1****Recruitment center****Name of recruitment center**

Rofeide Rehabilitation Hospital

Full name of responsible person

Amir Hossein Kahlaee

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

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Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

University of social welfare and rehabilitation sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

Academic

Person responsible for general inquiries**Contact****Name of organization / entity**

University of social welfare and rehabilitation sciences

Full name of responsible person

Amir Hossein Kahlaee

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Physiotherapy

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

University of social welfare and rehabilitation sciences

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Position

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Latest degree

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Other areas of specialty/work

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Person responsible for updating data

Contact

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Full name of responsible person
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

Intervention protocol and pre- and post-study tests, statistical methods, and informed consent forms will be shared prior to the intervention. The results of the statistical tests and the report of possible exit from the study will be reported after the end of the sampling and data analysis.

When the data will become available and for how long

Intervention protocol and pre- and post-study tests, statistical methods and informed consent forms will be shared in December 2019. Results of statistical tests and reports of possible withdrawal of subjects from study will be report winter 2021.

To whom data/document is available

It will be available to the public.

Under which criteria data/document could be used

The results of the study can only be used with reference to the present study. In order to perform any new statistical analysis on the data, a written authorization from the responsible researcher will be required.

From where data/document is obtainable

Interested in accessing study information can be reached by email at amir_h_k@yahoo.com or am.kahlaee@uswr.ac.ir or correspondence with Postal Address of Farabi Building, 5th Floor, Room 522 at Farabi Building, 5th Floor, Room 522

What processes are involved for a request to access data/document

Contacting the responsible researcher will be sufficient to access the data of this study. If the responsible researcher agrees to provide the information, this process will take a maximum of one week.

Comments